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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Colin Barrow

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Ballard Spahr LLP

SUITE 1000

999 PEACHTREE STREET

ATLANTA, GA 30309-3915

EXAMINER

CARR, DEBORAH D

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

05/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,204	Applicant(s) BARROW ET AL.	
	Examiner DEBORAH D. CARR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 7 9-14 16-17 19-20 24-39 41 43-45 47 49-58 64-65 69-70 72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 72 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,10,12,13,20,25-28,32-35,37,38,44,45,64,65,69 and 70 is/are rejected.
- 7) ☒ Claim(s) 2,5-7,9,11,14-17,19,29-31,36,39,41,43,47 and 49-58 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/07, 1/07, 10/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-4, 10, 12-13, 20, 25-28, 32-35, 37-38, 44-45 rejected under 35 U.S.C. 102(b) as being anticipated by DD – 230,137 or GB-1,274,718 or Rinse (US Pat. 4,022,725) or Loudon (US Pat. 3,547,666) or Burt (US Pat. 3,256,266) or Ceprini et al (US Pat. 3,932,285).

The references recited supra teach compounds and processes for making said compounds which fall within the scope of claims as follows:

- DD'137 - p. 9 l. 6, claim 8;
- GB'718 - example 24;
- US'725 - example 7;
- US'666 - example 6(iv);
- US'266 - claim 1, example 1, col. 2, lines 55 - col. 3, line 4;
- US'285 - abstract, col. 2 l. 24-68, example 14.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 64-65, 69-70 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 64-65, 69-70 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for improving insulin sensitivity, reducing hyperglycemia, and treating or preventing diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C)The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 64-65, 69-70 is drawn to improving insulin sensitivity, reducing hyperglycemia, and treating or preventing diabetes in a patient by administering a chromium complexed unsaturated fatty acid derivative.

The state of the prior art

The examiner notes that the art recognizes that dietary supplements of chromium picolinate or nicotinate and conjugated fatty acid mixtures have been known to treat insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia but not preventing any of these diseases. There is not teaching or recognition that complexed chromium unsaturated fatty acids are applicable to treating said disease. Applicants are invited to provide evidence to the contrary. In any event, the examiner notes that there is no art provided of record, evidence set forth in the disclosure, or correlation establishing some nexus to support prophylactic administration or therapy between the art and the instant disclosure to support the alleged treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or preventive applicability of the chromium complexed unsaturated fatty acid derivatives of the instant invention.

The level of one of ordinary skill

The skilled artisan in this field is that of an MD for treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases and/or a PhD skilled in the development of medicaments for treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases.

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The level of predictability in the art

The examiner acknowledges the probability and predictability that the instantly claimed chromium complexed unsaturated fatty acid derivatives have applicability in treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these disease conditions. There is not seen sufficient data to substantiate the assertion that treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases may be prevented by the use of a chromium complexed unsaturated fatty acid derivative. One skilled in this art would not predict from the disclosure provided that inflammatory diseases can be prevented in view of the data and examples provided.

The amount of direction provided by the inventor.

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the same to establish enablement for treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases. There is not seen guidance as to how the skilled artisan would formulate the requisite active agents and use it in methods for treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases. There is not seen sufficient guidance, which would teach the skilled artisan how to administer, said active agents in methods for treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases. To treat inflammatory diseases appears to be the limit of the applicability of the

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chromium complexed unsaturated fatty acid derivatives in methods of chemotherapy.

The existence of working examples

The working examples set forth in the instant specification are limited to the following combinations:

Examples of the process for preparing the instant compounds;

Examples of the derivatives of the chromium complexed unsaturated fatty acid core; and

Examples of the Biological activity of chromium complexed unsaturated fatty acid derivatives

There are no examples drawn to the treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these disease states and there is not seen sufficient correlative data to substantiate the preventive efficacy of any of the chromium complexed unsaturated fatty acid derivatives made by the methods set forth in the instant disclosure.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the treating insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these disease conditions and the skilled artisan would not extrapolate preventive efficacy from the results of the chromium complexed unsaturated fatty acid derivatives instantly claimed agonist activity against receptor sub-types. Nor is

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this data alone recognized in the art, as sufficient data to assert compounds with a specific activity would be expected to treat insulin-dependent diabetes, improving insulin sensitivity including hyperglycemia or prevention of these diseases.

Allowable Subject Matter

5. Claim 72 is allowed.
6. Claims 2,5-7,9,11,14, 15-17,19, 29-31,36,39, 41,43,47, 49-58 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc